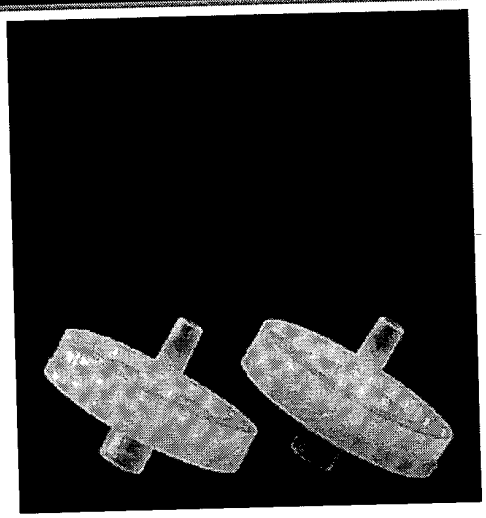
Sterile Acrodisc® Syringe Filters - Ideal for Scale Up

Description

Laboratory devices containing the same materials of construction as larger-capacity capsules and cartridges

- Three membrane chemistries assure compatibility with a wide range of fluids:
  - Supor® membrane has high flow rates and throughputs, and is ideal for solutions where low protein binding is required.
  - Ultipor® membrane, the industry standard for pharmaceutical filtration, provides broad solvent and chemical compatibility and low extractables.
  - Posidyne® membrane enhances bioburden and pyrogen removal from aqueous solutions.
- Simplify scale up and minimize requalification; no need to change membrane materials during transitions to pilot or production.
- Integrity testable (water bubble point).
- Bacterial retention tested to assure sterile filtrate.

BUY This Product



Specifications
To Contact Us
Part Number Information

Applications

- Small volume liquid steralization.
- Drug development studies.
- Determination of product compatibility and recovery.
- Preliminary filterability testing.

Complementary Products

- Filtron Brand: Centramate(TM) & Centramate PE Lab Tangential Flow Systems
- Filtron Brand: Maximate(TM) & Maximate-EXT Lab Tangential Flow Systems
- Filtron Brand: Mini-Ultrasette(TM) Lab Tangential Flow Devices
- Filtron Brand: Minisette(TM) Lab Tangential Flow Systems
- Filtron Brand: Ultralab(TM) Systems;

Ultrareservoir(TM) Containers; Ultrapump(TM) II Pumps
- Filtron Brand: Ultrasette(TM) Lab Tangential Flow Devices
- Life Sciences: SpiralCap® & SpiralCap PF Capsules with Supor® Membrane
- Life Sciences: SuporCap(TM) & CritiCap(TM) Sterile Capsules
- Membrane: Analytical Paper Filters
- Membrane: Biodyne® Transfer Membranes
- Membrane: BioTrace(TM) NT Nitrocellulose Transfer Membrane
- Membrane: BioTrace(TM) PVDF Transfer Membrane
- Membrane: DM Metricel® Membrane Disc Filters
- Membrane: FP Vericel(TM) (PVDF) Membrane Disc Filters
- Membrane: GH Polypro Membrane Disc Filters
- Membrane: GLA-5000 Membrane Disc Filters
- Membrane: Glass Fiber Filters
- Membrane: GN-4 Metricel® Membrane Disc Filters
- Membrane: GN-6 Metricel® Membrane Disc Filters
- Membrane: HT Tuffryn® Membrane Disc Filters
- Membrane: Ion Exchange Membrane Disc Filters
- Membrane: Metricel® Black Membrane Disc Filters
- Membrane: Metricel® Polypropylene Membrane Disc Filters
- Membrane: Nylaflo(TM) Membrane Disc Filters
- Membrane: Nylasorb(TM) Membrane Disc Filters
- Membrane: Pallflex® Filters
- Membrane: Polypropylene Separators Depth Filters
- Membrane: PTFE Membrane Disc Filters
- Membrane: Supor® Membrane Disc Filters
- Membrane: TCLP Glass Fiber Filters
- Membrane: UltraBind(TM) Affinity Membrane
- Membrane: Versapor® Membrane Disc Filters

Specifications

Materials of Construction

Filter Media:

PN 4905: Supor membrane (hydrophilic polyethersulfone)

PN 4906: Ultipor membrane (amphoteric Nylon 6,6)
PN 4908: Posidyne membrane (positively-charged Nylon 6,6)
Housing: Polypropylene

Effective Filtration Area
2.8 cm^2

Inlet/Outlet Connections
Female Luer-Lok* inlet, male slip luer outlet

Maximum Hold-up Volume
100 µL

Maximum Operating Temperature
60 °C (140 °F) at 4.1 bar (psi)

Maximum Operating Pressure
5.4 bar (80 psi) at ambient temperature

Typical Water Flow Rate
mL/min at 2.1 bar (30 psi)
PN 4905: 130
PN 4906: 78
PN 4908: 77

Recommended Integrity Test
Minimum Bubble Point -- Water
PN 4905: 3.0 bar (45 psi)
PN 4906, 4908: 3.3 bar (48 psi)

Bacterial Retention
Lot samples retain 10^7 cfu/cm^2 of *B. diminuta* per modified ASTM F838-83

Endotoxin
< 0.25 EU/mL using Limulus Amoebocyte Lysate (LAL) test

Biological Safety
Passes USP Class V1-121 °C Plastics Tests

Sterilization
Sterilized by gamma irradiation and individually blister packed

Part Number Information

Product No.	Description	Packaging
Sterile Acrodisc® Syringe Filters		
4905	SUPOR ACRODISC,.8/.2UM STRL	PK
4906	ULTIPOR ACRODISC, .2UM STRL	PK
4908	POSIDYNE ACRODISC,.2UM STRL	PK

NYLON 6 VERSUS NYLON 6,6

Practical Considerations

There have been some recent instances where Pall Nylon 6,6 polymer membrane filter customers may have listed "polyamide" or "Nylon" as the filter medium used in their processes and are considering use of alternate membrane filters made with Nylon 6 polymer. Of the greatest concern are those processes where customers have cited "polyamide" or "Nylon" as the filter medium used in their processes in FDA submissions and SOP's. In the description of polymers, and for that matter any chemical compound, imprecision can be both misleading and dangerous. Here are some important differences between the two polymers that must be considered.

Nylon 6 Is Not Nylon 6,6

Nylon 6 is not Nylon 6,6. While people may argue over the merits of replacing one PVDF filter with a different PVDF filter for example, this is not the situation in replacing a Nylon 6,6 filter with Nylon 6 filter. On the contrary, replacing Nylon 6,6 with Nylon 6 is more like replacing a PVDF filter with a PTFE filter!! Therefore, the issue of non-equivalence of Nylon 6 vs. Nylon 6,6 must be raised, at least wherever Nylon 6 is under consideration for use in place of validated Nylon 6,6, because the extractables, toxicology and chemical formulas of the two differ, as demonstrated below:

Nylon 6: $-[NH(CH_2)_5CO]_n-$

Nylon 6,6: $-[NH(CH_2)_6\ NHCO(CH_2)_4CO_n]-$

How Nylon 1 Is Manufactured

Nylon 6 is manufactured by the polymerization of epsilon-caprolactam monomer.

The resultant Nylon 6 polymer must then be treated to remove almost all of the water-extractable material, largely residual monomer left after polymerization.

Subsequent processing, e.g. conversion to membrane structure, must be done under conditions which minimize reversion to the equilibrium

epsilon-caprolactam monomer content. This is not to imply that Nylon 6 filter cartridges necessarily have residual epsilon-caprolactam monomer, but rather to clearly differentiate it from Nylon 6,6, which utilizes an entirely different monomer system.

How Pall Nylon 6,6 Is Manufactured

Nylon 6,6, which is used by Pall, is manufactured by the condensation of hexamethylene-diamine and adipic acid monomers. Neither of these two monomers were detected in extraction studies of Nylon 6,6 performed by the resin manufacturers and subsequently reviewed by the FDA. More directly, Pall Nylon 6,6 filter cartridges were not mutagenic in a series of Ames Salmonella assays conducted by an outside, independent laboratory and reported in our Validation Guide for Pall 0.2 µm Ultipor® N_{66}® and N_{66} Posidyne® Membrane Cartridges (Pall Publication TR-680c). This extensive testing was performed in addition to the *United States Pharmacopeia (USP)* Biological Reactivity Tests, In Vivo, for Class VI - 121 °C Plastics, also reported in TR-680c. The key point here is does such analysis and bio-safety data exist for Nylon 6 filters??

Regulatory Implications

Finally, and perhaps most importantly to FDA-regulated companies, is that at a December, 1996 joint conference of the FDA Center for Devices Compliance Office (the group which regulates manufacturers of diagnostic products) and the Food & Drug Law Institute (FDLI), the FDA advised firms to track and keep records of even minor manufacturing changes made by component suppliers. Therefore, a regulated company, would need to keep records if it changed a component material or supplier. Such a change could be considered a design change, and all design changes must either be reverified or revalidated.

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